

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Six-Week Aerobic Exercise and consumption of nano-curcumin on Interleukin 6, Interleukin 10, Tumor necrosis factor-alpha, Interleukin 1B, Brain-derived neurotrophic factor, Depression, Medium and short-term memory in 60-65 Years Old Women with metabolic syndrome.

Protocol summary

Summary

The main purpose of this research was to investigate the effect of six-week aerobic exercise with moderate intensity and consumption of 80 mg nano-curcumin after breakfast on Interleukin 6, Interleukin 10, Tumor necrosis factor-alpha, Interleukin 1B, Brain-derived neurotrophic factor, Depression, Medium and short-term memory in 60-65 year-old women with metabolic syndrome. nano-curcumin consumption was double blinded. Participants were randomly divided into 4 groups of metabolic syndrome exercise plus nano-curcumin, metabolic syndrome exercise, metabolic syndrome nano-curcumin, and metabolic syndrome control. During the first week metabolic syndrome exercise+ nano-curcumin group and metabolic syndrome exercise participated in three sets of twelve-minute aerobic exercise training with treadmill. They also had 5-minute rest parts between the sets. One minute was added to the duration of exercise sets on a weekly basis. Blood samples were conducted before and after six-week interventions. Interleukin 6, Interleukin 10, Tumor necrosis factor-alpha, Interleukin 1B, Brain-derived neurotrophic factor levels were measured by Enzyme-linked Immunosorbent Assay method and memory test were conducted with a Picture recall test and Digit span Memory test. Also the amount of depression was measured with Beck Depression Test-Questionnaire. Exclusion criteria: Being absent for 3 sessions during 6 weeks; Not consuming (nano-curcumin) according to the instructions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082335857N1**

Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Ali Osali

Name of organization / entity

Bonab University

Country

Iran (Islamic Republic of)

Phone

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Email address

osaliphd@bonabu.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Six-Week Aerobic Exercise and consumption of nano-curcumin on Interleukin 6, Interleukin 10, Tumor necrosis factor-alpha, Interleukin 1B, Brain-derived neurotrophic factor, Depression, Medium and short-term memory in 60-65 Years Old Women with metabolic syndrome.

Public title
The Effect of Six-Week Aerobic Exercise and consumption of nano-curcumin on Interleukin 6, Interleukin 10, Tumor necrosis factor-alpha, Interleukin 1B, Brain-derived neurotrophic factor, Depression, Medium and short-term memory in 60-65 Years Old Women with metabolic syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Being female; Being 60-65 years old; and metabolic syndrome; Not doing regular exercise.
Exclusion criteria: Being absent for 3 sessions during 6 weeks; Not consuming (nano-curcumin) according to the instructions.

Age
From **60 years** old to **65 years** old

Gender
Female

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study randomization was performed using sealed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University Medical Sciences
Street address

Semnan Province, Semnan, Basij Blvd
City
Semnan
Postal code
3514799442
Approval date
2017-07-12, 1396/04/21
Ethics committee reference number
IR.SEMUMS.REC.1396.107

Health conditions studied

1

Description of health condition studied
syndrome metabolic

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
IL6

Timepoint

Before intervention and after six week intervention

Method of measurement

pg- Enzyme-linked Immunosorbent Assay

2

Description
IL10

Timepoint

Before intervention and after six week intervention

Method of measurement

pg- Enzyme-linked Immunosorbent Assay

3

Description
IL1B

Timepoint

Before intervention and after six week intervention

Method of measurement

pg- Enzyme-linked Immunosorbent Assay

4

Description
TNF-a

Timepoint

Before intervention and after six week intervention

Method of measurement

pg- Enzyme-linked Immunosorbent Assay

5

Description

BDNF
Timepoint
Before intervention and after six week intervention
Method of measurement
pg- Enzyme-linked Immunosorbent Assay

Secondary outcomes

1

Description
Short-Term Memory
Timepoint
Before intervention and after six week intervention
Method of measurement
Powerpoint Software-Recall Numbers Test

2

Description
Medium-Term Memory
Timepoint
Before intervention and after six week intervention
Method of measurement
Powerpoint Software-Picture Recall Test

3

Description
Depression
Timepoint
Before intervention and after six week intervention
Method of measurement
Beck Depression Test- Questionnaire

Intervention groups

1

Description
Intervention group: Drug group, nano-curcumin was taken once a day (morning) pill - 80 mg for six weeks. The nano-curcumin manufacturing license used in the study was for the Exquisite Nano Sina Company and the location of the building was at the Minoo Iran Pharmacy Company.
Category
Treatment - Drugs

2

Description
Intervention group: Exercise and Drug group, six-week aerobic exercise with moderate intensity during the first week MECU group and ME participated in three sets of twelve-minute aerobic exercise training with treadmill, they also had 5-minute rest parts between the sets. One minute was added to the duration of exercise sets weekly basis. nano-curcumin was taken once a day (morning) pill - 80 mg for six weeks. The nano-curcumin manufacturing license used in the study was for the Exquisite Nano Sina Company and the location of the

building was at the Minoo Iran Pharmacy Company.
Category
Treatment - Other

3

Description
Intervention group: Exercise group, six-week aerobic exercises with moderate intensity During the first week MECU group and ME participated in three sets of twelve-minute aerobic exercise training with treadmill. They also had 5-minute rest parts between the sets. One minute was added to the duration of exercise sets weekly basis.
Category
Treatment - Other

4

Description
Control group: This group did not received any interventions within 6 weeks of the study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Bonyadshahid and Umoreisargharan ostan Zanjan
Full name of responsible person
Ali Osali
Street address
Bonyadshahid and Umoreisargharan ostan
Zanjan,Zanjan, Zanjan
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reserch of University of Bonab
Full name of responsible person
Dr.Hossein Ghaforian
Street address
Bonab University
City
Bonab
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reserch of University of Bonab
Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Azarbaijan Shahid Madani

Full name of responsible person

Dr.Karim Azali Alamdari

Position

Assistant Professor of Azarbaijan Shahid Madani University

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Dr.Karim Azali Alamdari

Position

Phd

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Bonab

Full name of responsible person

Dr.Ali Osali

Position

Phd

Other areas of specialty/work

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